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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/755,233	01/08/2001	Padmanabhan P. Nair	NAIR-5	4931

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

09/755,233

Office Action Summary

Application No.

09/755,233

Applicant(s)

NAIR, PADMANABHAN P.

Examiner

Susan Ungar

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 05 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 7-9 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 7-9, 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

1. The Response filed January 5, 2004, in response to the Office Action of September 3, 2003 is acknowledged and has been entered. Claims 7-9 26-28 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are maintained:

Claim Rejections - 35 USC § 101

4. Claims 7-9 and 26-28 remain rejected under 35 USC 101 for the reasons previously set forth in the paper mailed September 3, 2003, Section 4, pages 2-6.

Applicant argues that absence of IgA is the most common defect in immunodeficiency diseases and that immunodeficiency diseases are well known therefore monitoring immunoglobulin production by any means is a well established utility that requires no further experimentation and submits a reference, Buckley, to establish that immunodeficiency diseases are well known. The discovery of immunocoprocytes as described in the present application is novel and facilitates noninvasive assessment of mucosal immunity. The argument has been considered but has not been found persuasive for the reasons of record. In particular, as previously set forth, neither the specification nor the art of record teaches what monitoring the mucosal immunity with immunocoprocytes will impart, does not teach what GI pathology might be associated with alterations in immunocoprocyte expression of the claimed molecules or what alteration in the proliferation of immunocoprocytes might mean. The Buckley reference does not teach that the claimed immunocoprocytes are useful for monitoring mucosal immunity or how to use the claimed immunocoprocytes to monitor mucosal immunity. Further, given Applicant's teaching that the absence of IgA is the most

common defect in immunodeficiency diseases, it is clear that this defect is not specific to immunocoprocytes and therefore would not impart a specific utility to the claimed invention. Further, there is no teaching in the specification as originally filed that IgA expression in fact is suppressed in immunocoprocytes in association with any immunodeficiency disease.

Applicant further argues that since the invention describes the normal limits of distribution of immunocoprocytes in Table 2, a deviation or suppression of these cells would be expected and since the various immunoglobulins and the receptors have been characterized in Figure 3, a skilled artisan would be enabled to use the immunocoprocytes of the present invention for noninvasive assessment of mucosal immunity. The argument has been considered but has not been found persuasive, Applicant has not taught that these cells are suppressed in association with immunodeficiency diseases or that the various immunoglobulins deviate or are suppressed in these cells. For these reasons, additional experimentation is required in order to determine a real world use for the claimed invention. Applicant's arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 112

5. Claims 7-9 and 26-28 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed September 3, 2003, Section 6, page 6.

Applicant argues that in view of the arguments submitted above, one skilled in the art would know how to use the claimed invention. The argument has been considered but has not been found persuasive for the reasons set forth above. Applicant's arguments have not been found persuasive and the rejection is maintained.

6. Claims 7-9 and 26-28 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed September 3, 2003, Section 7, pages 6-10.

Applicant notes that Kobayashi et al describes a unique IgG binding Fc receptor in contrast to the discovery of a unique IgC of the present invention which is a chimera consisting of IgA and IgG subunits. Examiner notes that Examiner never suggested that the unique IgG binding Fc is an IgC, but rather that, given the claimed CFc of the instant invention, it appears that the colonocytes of Kobayashi et al with the unique IgG binding Fc receptor, are the same as the claimed invention.

Applicant further argues that the specification teaches how to isolate immunocoprocytes and the relative distribution of these immunoglobulins and CFc is taught in Table 2 and the structures of these components are also diagrammatically presented in Figure 3. The argument has been considered but has not been found persuasive for the reasons of record. In particular, isolation of the colonocytes is not a teaching of how to make the claimed invention. Further, a review of the line diagrams in Figure 3 reveals that these diagrams do not provide sufficient information drawn to the structure of IgC or CFc. Finally, the relative distribution of the immunoglobulins does not make up for the deficiencies of the specification as originally filed.

It is noted that Applicant has not addressed the issued raised by Examiner drawn to (a) how to use the claimed immunocoprocytes to monitor mucosal immunity, (b) how to use the immunocoprocytes as diagnostic and predictor indicators of GI tract pathology or how to use them for any of the other vital functions described on page 16 of the specification.

Art Unit: 1642

Applicant's arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 102

7. Claims 7-9 and 26-28 remain rejected under 35 USC 102(b), first paragraph for the reasons previously set forth in the paper mailed September 3, 2003, Section 9, pages 10-11

Applicant argues that since the reference is drawn to expression of CD44 in colon cancer and has no reference to expression of CFC or about immunocoprocytes, it is not understood how Dutta et al anticipates the present invention which is related to imunocoprocytes, a unique cellular entity discovered by the applicant.

The argument has been considered but has not been found persuasive because the colonocytes of Dutta et al were isolated from the same population as the claimed immunocoprocytes which are a subset of colonocytes and therefore a subset of the colonocytes of Dutta et al will include each type of immunocoprocyte claimed. It is noted, again, that the claims are drawn to immunocoprocytes, which are a subset of colonocytes, and that limitations drawn to the function of those immunocoprocytes are not given weight in comparing the claims with the prior art. Applicant's arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 103

8. Claims 7, 9, 27-28 remain rejected under 35 USC 103 for the reasons previously set forth in the paper mailed September 3, 2003, Section 11, pages 12-13.

Applicant argues that (a) the method of Dutta et al is incapable of producing the type and purity of colonocytes which express CFC, (b) even if sufficiently pure isolated colonocytes are obtained, further techniques must be used to obtain a distinctive group of cells identified as immunocoprocytes which are unique in expressing heretofore unknown chimeric immunoglobulin IgC. The argument has been considered but has not been found persuasive, (a') Applicant's hypothesis that the method of Dutta is incapable of producing the type and purity of colonocytes which express CFC is unconvincing in the absence of objective evidence demonstrating that the colonocytes isolated by the method of Dutta et al do not include a subset of colonocytes which are in fact immunocoprocytes as defined by the specification, further, Applicant is arguing limitations not recited in the claims as currently constituted since the claims are not drawn to a product produced by a process, (b') Applicant is arguing and discussing the Dutta et al reference without clearly addressing the combined teachings of the Dutta et al and Kobayashi et al reference. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Applicant's arguments have not been found persuasive and the rejection is maintained.

9. Applicant submits the Par reference and the Lakatos reference in order to show the utility of measuring immune function in a variety of diseases. The references have been reviewed and although it is clear that utility of measuring

Art Unit: 1642

immune function in a variety of diseases is well known, neither reference teaches that the claimed immunocoprocytes are useful for measuring immune function or how to use the claimed immunocoprocytes to measure immune.

10. No claims allowed.

11. All other objections and rejections recited in the paper mailed September 3, 2003 are hereby withdrawn.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.


13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvette Eyler, can be reached at 571-272-0871. The fax phone number for this Art Unit is (703) 305-7230.

Art Unit: 1642

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.


Susan Ungar
Primary Patent Examiner
March 8, 2004